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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,575	09/17/2003	Jonathan Fanger	101896-0208	3611
21125	7590	05/04/2006	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			SWIGER III, JAMES L	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/664,575	<b>Applicant(s)</b> FANGER ET AL.	
	<b>Examiner</b> James L. Swiger	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 3/3/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,8,11-15,20-24,26,30,31 and 34-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7,9,10,16-19,25,27-29,32 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/17/06; 1/22/04; 9/20/04; 10/8/04; 1/17/06</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 4-5, 8, 11-15, 20-24, 26, 30-31, 34-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/3/2006.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 16-19, 25, 27, 28-29, and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Brace et al. (US 6,379,364). Brace et al. disclose a guide device comprising an elongate shaft (114) having a proximal (near 136) and distal (near 206/208) ends, a guide member (110) having a first and second lumens (250 and 252),

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capable of being aligned with the holes on a spinal plate. The device of Brace et al. also has at least one tab (218) that extends distally from the guide member that may also non-fixedly interact with a spinal plate, has a shape, has first and second lumens that are positioned at an angle with respect to one another (see Fig. 10) and wherein the lumens are shaped like barrels. Further, the alignment elements shown in Fig. 10 are capable of loosely interacting with a spinal plate.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Brace et al. '364. Brace et al. disclose the claimed invention except for an alignment element with an oval protrusion. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the device of Brace et al. having an oval protrusion, since applicant has not disclosed that such a shape solves any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of connecting the alignment element to the spinal plate. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 6 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brace et al. '264 in view of Oxland et al. (US 5,676,666). Brace et al. disclose the claimed invention except for a guide device wherein the alignment tabs are

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extending from opposing outer edges and the first and second lumens are placed between these protruding alignment tabs. Oxland et al. disclose a device that has tabs (76 and 78) that protrude on the outer opposing sides of the lumens (see Fig 1a). These tabs help with the proper alignment of the device (Col. 3, lines 15-20 and lines 29-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Brace et al. having at least tabs on opposing outer sides in view of Oxland et al. to better align the device in use on a spinal plate.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brace et al. '364 in view of Gill et al. (US 2003/0187454). Brace et al. disclose the claimed invention except for an extra protrusion that extends distally from the guide member. Gill et al. disclose a device that has a protrusion (79) that helps to guide the device and ensure a proper spacing relationship (par. 0047). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Brace et al. in view of Gill et al. to have better orientation between the device and the plate in their attachment.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 8:30am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JLS

4/30/2006



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER